IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO CIVIL DIVISION

ORIGINAL

TIMOTHY W. BYRD 482 #A OXFORD DRIVE LEBANON, OHIO 45036

Case No.A 1 4 0 2 9 3 8

Judge:

Plaintiff,

COMPLAINT & JURY DEMAND

ABUBAKAR ATIQ DURRANI, M.D.

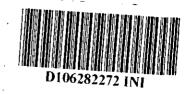
(Served by Hague Convention)

v.

Defendant

FACTUAL ALLEGATIONS OF PLAINTIFF

- 1. At all times relevant, Plaintiff, ("Plaintiff" or "Mr. Byrd") was a resident of an domiciled in the State of Ohio.
- 2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani ("Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
- 3. The subject matter of the Complaint arises out of medical treatment by the Defendant in Hamilton County, Ohio. This Court is thus the proper venue to grant the Plaintiff the relief she seeks.
- Plaintiff was injured in a work accident on December 1, 2006. He was taken to University Hospital for emergency treatment.
- 5. Dr. Durrani was working as a surgeon for University Hospital and examined Plaintiff.
- 6. Dr. Durrani recommended immediate surgery for Plaintiff.



The Man

- 7. On or about December 3, 2006 Dr. Durrani performed spinal fusion surgery on Plaintiff at University Hospital.
- 8. Plaintiff had an increase in pain and a loss in range of movement following surgery.
- 9. When Plaintiff inquired about this, Dr. Durrani told Plaintiff to "go back to school because you will never work again."
- Plaintiff continues to suffer from back pain because of the surgery performed by Dr.
 Durrani.
- 11. Dr. Durrani recommended a possible follow up surgery but Plaintiff elected against treating with him again.
- 12. Plaintiff continues to suffer from constant back pain.
- 13. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off –label" and/or Puregen without Mr. Byrd's knowledge or consent, causing Mr. Byrd harm.
- 14. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
- 15. As a direct and proximate result of Mr. Byrd's surgery and Dr. Durrani's negligence, Mr. Byrd has suffered harm.
- 16. Plaintiff did not become aware of Infuse/BMP-2 and/or Puregen until he contacted his undersigned counsel.

INFUSE/BMP-2

- 17. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.
- 18. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."
- 19. Dr. Durrani is a consultant for Medtronic.

- 20. Defendant did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.
- 21. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.
- 22. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.
- 23. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.
- 24. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")
- 25. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."
- 26. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When

nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

- 27. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.
- 28. Dr. Durrani and University Hospital personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.
- 29. Dr. Durrani used BMP-2 in Plaintiff in manners not approved by Medtronic or the FDA.
- 30. Defendant did not inform Plaintiff that Dr. Durrani used Infuse/BMP-2 in his surgeries.
- 31. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.
- 32. Plaintiff would not have consented to the use of BMP-2 in his body if informed of the risks by Dr. Durrani or any University Hospital personnel.
- 33. The written informed consent of Dr. Durrani and University Hospital signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedure.
- 34. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any University Hospital personnel.
- 35. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

- 36. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.
- 37. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.
- 38. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.
- 39. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

- 40. Dr. Durrani oftentimes used Puregen when performing surgeries.
- 41. Puregen is a product produced by Alphatec Spine.
- 42. Dr. Durrani was and is a paid consultant for Alphatec Spine.
- 43. Dr. Durrani has an ownership stake in the Alphatec Spine.
- 44. Puregen has never been approved by the FDA for any human use.
- 45. Puregen is now removed from the market for any use.
- 46. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.
- 47. Dr. Durrani and University Hospital personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.
- 48. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.
- 49. Plaintiff was not informed by Dr. Durrani or any University Hospital personnel that Dr. Durrani used Puregen in Plaintiff's surgery.
- 50. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA.

- 51. Plaintiff would not have consented to the use of Puregen in his body if informed of the risks by Dr. Durrani or any University Hospital personnel.
- 52. The written informed consent of Dr. Durrani signed by Plaintiff lacked the disclosure of Puregen's use in his procedures.
- 53. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani or any University Hospital Personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

- 54. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.
- 55. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.
- 56. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

COUNT II: BATTERY

57. Dr. Durrani committed battery against Plaintiff by performing surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did

- not properly obtain informed consent, inter alia, by using Infuse/BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.
- 58. Plaintiff would not have agreed to the surgery if he knew the surgery was unnecessary, not approved by the FDA, and not indicated.
- 59. As a direct and proximate result of the aforementioned battery by Dr. Durrani,
 Plaintiff sustained all damages requested in the prayer for relief.

COUNT III: LACK OF INFORMED CONSENT

- 60. The informed consent forms from Dr. Durrani which he required Plaintiff to sign, failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani required an informed consent release.
- 61. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before the Plaintiff's surgery.
- 62. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with his surgery and procedures.
- 63. Plaintiff subsequently developed severe and grievous injuries as a direct and proximate result of lack of informed consent.
- 64. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

65. Dr. Durrani's conduct as described above was intentional and reckless.

- 66. It is outrageous and offends against the generally accepted standards of morality.
- 67. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.
- 68. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

- 69. Dr. Durrani made material, false representations to Plaintiff and his insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.
- 70. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery when he had a duty to disclose to Plaintiff his planned use of the same.
- 71. These misrepresentations and/or concealments were material to Plaintiff because they directly induced the Plaintiff to undergo his surgery.
- 72. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

- 73. Dr. Durrani made the misrepresentations before, during, and after the surgery, with the intent of misleading Plaintiff and his insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.
- 74. The misrepresentations and/or concealments were made during the Plaintiff's office visits at Dr. Durrani's offices and/or at University Hospital.
- 75. Plaintiff was justified in his reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.
- 76. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery, which was paid for in whole or in part by his insurance company, and suffered all damages requested in the prayer for relief.

COUNT VI: SPOLIATION OF EVIDENCE

- 77. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, emails, paperwork and related evidence.
- 78. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.
- 79. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendant on all claims for the following damages:

- 1. Past medical bills;
- 2. Future medical bills;
- 3. Lost income and benefits;
- 4. Lost future income and benefits;
- 5. Loss of ability to earn income;
- 6. Past pain and suffering;
- 7. Future pain and suffering;
- 8. Plaintiff seeks a finding that his injuries are catastrophic under Ohio Rev. Code \$2315.18;
- 9. All incidental costs and expenses incurred as a result of his injuries;
- 10. The damages to his credit as a result of his injuries;
- 11. Punitive damages:
- 12. Costs;
- 13. Attorneys' fees;
- 14. Interest;
- 15. All property loss;
- 16. All other relief to which he is entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of \$25,000.

Respectfully Submitted,

Stephanie L. Collins (0089945)

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JURY DEMAND

Plaintiff makes a demand for a jury under all claims.

Stephanie L. Collins (0089945)